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10/501,887

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Vladimir Velebny

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10/16/2008

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EXAMINER

FINN, MEGHAN R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/501,887 | Applicant(s) VELEBNY ET AL. | |
| | Examiner MEGHAN FINN | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-30 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) 6-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,27-30 and 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/27/08; 7/25/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Amendment filed July 25, 2008 has been received and entered into present application. Claims 5 and 31 were canceled and claims 6-26 remain withdrawn. Thus claims 1-4, 27-30, and 32-37 are pending.

Applicants' arguments, filed July 27, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The Information Disclosure Statement (IDS) filed on July 25, 2008 is identical to the IDS filed on June 27, 2008. The June 27th, 2008 IDS was considered, and the July 25th, 2008 IDS was crossed out, because that reference was already considered.

Claim Objections

Claim 1 is objected to because of the following informalities: applicant corrected one of the misspellings indicated in the previous office action, but did not fix "would covering" on line 4 of claim 1. Since "would covering" makes no sense, it is assumed this was just an oversight and that applicant is not intending to indicate that they meant to claim "would covering". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 27-30, and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyata et al. (US 2002/0098244 A1), in view of Cantor et al. (US 2003/0054025 A1).

In claim 1, applicant claims a composition for minimizing wound adhesion, comprising hyaluronic acid with a molecular weight ranging from 200,000-2,500,000, iodine and potassium iodide, wherein the composition is in the form of a sterile solution or a gel. Miyata et al. teach a gel made of hyaluronic acid (abstract) and teach that

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hyaluronic acid is an adhesion preventative (page 5, [0078-0079]). They specifically teach the use of hyaluronic acid for a wound dressing (page 5, [0070]). Miyata et al. also teach using sodium hyaluronate of a molecular weight of 2,000,000 (example 1, page 5, [0083]). However, Miyata et al. does not teach the specific combination of iodine or potassium iodide claimed. However, Cantor et al. teach antimicrobial agents such as iodine complexes with potassium iodide (page 5, [0048]). In fact they teach iodine complexes with potassium iodide as preferred antimicrobial agents (page 5, [0048]). It would have been obvious to one of ordinary skill in the art at the time of the invention that adding the iodine complexed with potassium iodide of Cantor et al. to the gel of Miyata et al. would improve the wound dressing as antimicrobial agents are commonly included in wound dressings and would result in a better wound dressing composition. Miyata et al. does not specifically state that the wound dressing would be a sterile gel, however it would also have been obvious to one of ordinary skill in the art at the time of the invention that it would be advantageous for wound dressings to be sterile. Thus claim 1 is unpatentable over Miyata et al. in view of Cantor et al.

In claim 2, applicant claims the hyaluronic acid is in the form of a salt, including sodium salt. Miyata et al. teach using sodium hyaluronate in example 1 (page 5, [0083]), which is the sodium salt form of hyaluronic acid and thus claim 2 is unpatentable over Miyata et al. in view of Cantor et al.

In claims 3-4, applicant claims a concentration of hyaluronic acid from 0.05-10% by weight and a concentration of 0.075-1% by weight of iodine, as well as a

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concentration of 0.075-1% by weight of potassium iodide. Miyata et al. teaches 0.05% as the preferred concentration of hyaluronic acid, but also teaches concentrations up to 0.01% (page 5, [0069]). Cantor et al. does not teach concentrations of iodine or potassium iodide, however it would be obvious to one of ordinary skill in the art at the time of the invention that the iodine and potassium iodide would be present in smaller concentrations than that of the hyaluronic acid since the gel is intended to be a carrier for active agents (page 5, [0075]), thus concentrations of 0.05 or below would be obvious to one of ordinary skill in the art. Furthermore, applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Thus claims 3 and 4 are unpatentable over Miyata et al. in view of Cantor et al.

In claim 27, applicant claims a composition comprising iodine, potassium iodide, and hyaluronic acid, wherein the composition is formulated as a gel. As discussed above, Miyata et al. teaches a gel wound dressing containing hyaluronic acid, and it would have been obvious to one of ordinary skill in the art at the time of the invention to add an antimicrobial agent such as the iodine and potassium iodide complex of Cantor et al. to enhance the wound dressing capabilities. Thus for the reasons discussed above claim 27 is also unpatentable over Miyata et al. in view of Cantor et al.

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Claims 28, 30, and 32-35 are merely claiming the same concentrations and salt forms claimed above in claims 1-4 and 27, and thus are also unpatentable over Miyata et al. in view of Cantor et al. for the reasons discussed above.

In claim 29, applicant claims that the iodine is added to the potassium iodide to form an iodine solution before adding it to the hyaluronate solution, and in claim 35 applicant claims that the iodine solution is combined with the hyaluronic acid solution. Cantor et al. teaches a complex of iodine and potassium iodine, and while they do not explicitly state that the two were combined, the language of complex would convey to one of ordinary skill in the art at the time of the invention that the two iodine solutions are mixed together, and would be added as a complex to the hyaluronic acid solution of Miyata et al. and thus claims 29 and 35 are unpatentable over Miyata et al. in view of Cantor et al.

In claim 37, applicant claims the composition of claim 27 is viscous. Applicant has not specifically defined "viscous" to have a specific property, so the broadest reasonable interpretation of that term would include any solution with which appears thick, or keeps shape upon dispensing, and a gel (such as the one taught by Miyata et al.) would be considered viscous, thus claim 37 is also unpatentable over Miyata et al. in view of Cantor et al.

Conclusion

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No claims are allowed.

Because of the rejection necessitated by applicant's arguments, this rejection is non-final.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

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/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614